UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TIFFANY HOOD-PENDERGHEST LISA FLAX, and BRIAN VARDARO on behalf of themselves and all others similarly situated,	:	
Plaintiffs,	:	**Case No. 21-17401**
v.	:	**CLASS ACTION COMPLAINT**
KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC,	:	**DEMAND FOR JURY TRIAL**
Defendants.	:	

Plaintiffs Tiffany-Hood Penderghest, Lisa Flax, and Brian Vardaro ("Plaintiffs"), on behalf of themselves, the class and subclasses of all others similarly situated as defined below, for their complaint against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), and Philips RS North America LLC ("Philips RS") (collectively "Philips" or the "Defendants"), allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

INTRODUCTION

1. Plaintiffs bring this action on behalf of themselves and the proposed classes of purchasers and users of Continuous Positive Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (Bi-Level PAP) devices and mechanical ventilators manufactured by Philips, which contain polyester-based polyurethane sound abatement foam ("PE-PUR Foam").

2. On June 14, 2021, Philips recalled its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam (the "Recall") via a recall notice (the "Recall

Notice"). Phillips disclosed that these devices uniformly presented a serious health risk to consumers because (a) the PE-PUR Foam was at risk for degradation into toxic particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain toxic chemicals during operation. Philips further first revealed in its Recall Notice that "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."

3. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the degraded foam reveals the presence of harmful chemicals, including: Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").

4. The Food and Drug Administration ("FDA") has designated the Phillips' Recall under its most serious classification, which means there is a reasonable probability that past or continued use of the device could lead to serious health issues.

5. Prior to issuing the Recall Notice, Philips received complaints regarding the presence of black debris/particles within the airpath circuit of its devices (extending from the device outlet, humidifier, tubing, and mask). Philips also received reports of headaches, upper airway irritation, cough, chest pressure and sinus infection from users of these devices.

6. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to users of these devices include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic affects. The known risks associated with chemical exposure due to off-gassing of PE-PUR Foam in these devices include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

7. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue using their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options.

8. Plaintiffs did not learn of the Recall until weeks after it was issued.

9. Plaintiffs seek to recover damages based on, inter alia, Philips' breach of express warranty, breach of implied warranties, misrepresentations, omissions, and breaches of state consumer protection laws in connection with its manufacture, marketing and sales of devices containing PE-PUR Foam on behalf of themselves and the proposed Class and Subclasses. In addition, Plaintiffs seek medical monitoring damages for users of Philips' devices identified in the Recall Notice, who are at risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic affects.

PARTIES

10. Plaintiff Tiffany Hood-Penderghest purchased and used a Philips DreamStation CPAP Machine, which she used nightly until she learned of the Recall on or about July 30, 2021. Mrs. Hood-Penderghest lived in West Chester, Pennsylvania when she purchased the device and currently resides at 7 Orchard Drive, Mullica Hill, NJ.

11. Plaintiff Lisa Flax purchased and used a Philips DreamStation CPAP Machine, which she used nightly until she learned of the Recall on or about July 9, 2021. Ms. Flax resides at 15A E. Daisy Lane, Mt. Laurel, NJ 08054 and purchased her DreamStation in New Jersey.

12. Plaintiff Brian Vardaro purchased and used a Philips DreamStation CPAP Machine, which he used nightly until he learned of the Recall on or about July 6, 2021. Prior to using the DreamStation, Mr. Vardaro also purchased and used the Respironics System One, which

was also included in the Recall. Mr. Vardaro resides at 5 Bowdoin Street, Danvers, MA 01923 and purchased his DreamStation CPAP Machine and Respironics System One in Massachusetts.

13. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS. Upon information and belief, Royal Philips controls Philips NA and Philips RS in the research, development, designing, manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.

14. Defendant Philips NA is a Delaware limited liability company with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips.

15. Defendant Philips RS is a Delaware limited liability company with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly-owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

JURISDICTION AND VENUE

16. This Court has subject-matter jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (1) the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are members of the Class and Subclass who are diverse from Defendants, and (4) there are more than 100 class members. This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. §

1367, because they form part of the same case or controversy as the claims within the Court's original jurisdiction.

17. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965, because Defendants transact business in this District, a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District; and because the Defendants caused harm to class members residing in this District.

18. The Court has personal jurisdiction over the Defendants because Defendants conduct substantial business in this District, and the events giving rise to Plaintiffs' claims arise out of and relate to Defendants' contacts with this District. Defendants Philips RS and Philips NA are controlled by their parent Royal Philips. Defendants' affiliations with this District are so continuous and systematic as to render them essentially at home in the forum State. Further, Defendants have transacted business, maintained substantial contacts, purposefully targeted consumers and medical professionals for sales of its devices and/or committed overt acts in furtherance of the unlawful acts alleged in this Complaint in this District, as well as throughout the United States. The unlawful acts of Defendants have been directed at, targeted, and have had the effect of causing injury to persons residing in, located in, or doing business in this District, as well as throughout the United States.

19. Personal jurisdiction exists over all Defendants pursuant to 18 U.S.C. § 1965(b) and Fed. R. Civ. P. 4(k).

FACTUAL BACKGROUND

20. CPAP therapy is a common nonsurgical treatment used to treat sleep apnea. CPAP therapy involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help him or her breathe.

21. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

22. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

23. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the

patient's lungs to help him breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

24. Philips developed, designed, manufactured, marketed, and sold a variety of CPAP and Bi-Level PAP respirator devices and mechanical ventilators under the "Sleep & Respiratory Care" segment of its business designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments. Philips' CPAP and Bi-Level PAP respirator devices and its mechanical ventilators typically cost several hundred, if not thousands of dollars. Philips has sold millions of these devices in the United States.

25. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."[1]

[1] First Quarter Results, PHILIPS (Apr. 26, 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf.

26. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices."[2] Specifically, Philips announced that it had determined that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals."[3] In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.[4]

27. The list of the devices recalled by Philips (the "Recalled Devices") include:

Philips CPAP and Bi-Level PAP Devices Manufactured Before April 26, 2021 Subject to Recall[5]	
Device Name/Model Type	**Type**
E30 (Emergency Use Authorization)	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
DreamStation ASV	
DreamStation ST, AVAPS	
SystemOne ASV4	
C Series ASV	
C Series S/T and AVAPS	

[2] *Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices*, PHILIPS (June 14, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html.

[3] *Id.*

[4] Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due-health-risks-n1270725.

[5] Recall Notice (Exhibit "A" hereto); see also Medical Device recall notification (U.S. only) / field safety notice (International Markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2; Royal Philips Update on the recall notification, https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html.

OmniLab Advanced Plus	
SystemOne (Q Series)	Non-continuous Ventilator
DreamStation	
DreamStation GO	
Dorma 400	
Dorma 500	
REMStar SE Auto	

Philips Mechanical Respirator Devices Manufactured Before April 26, 2021 Subject to Recall[6]	
Device Name/Model Type	**Type**
Trilogy 100 Ventilator	Continuous Ventilator
Trilogy 200 Ventilator	
Garbin Plus, Aeris, LifeVentVentilator	
A-Series BiPAP Hybrid A30	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP V30 Auto	
Philips A-Series BiPAP A40	Continuous Ventilator, Non-life Supporting
Philips A-Series BiPAP A30	

28. According to Philips, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from: "[i]rritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects."[7]

29. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."[8]

30. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact,

[6] *Id.*

[7] *Id.*

[8] Philips *Sleep and Respiratory Care Update – Clinical information for physicians*, June 14, 2021, philips-recall-clinical-information-for-physicians-and-providers.pdf.

from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment."[9]

31. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."[10]

32. As a result of the health risks associated with the use of the Recalled Devices, the Recalled Devices were economically worthless at the point for sale by virtue of the dangerousness caused by the PE-PUR Foam degradation. Therefore, the sale of the Recalled Devices to Class Members should never have occurred, and the transactions were void ab initio.

33. The information described above, including the now-known health risks of Philips CPAP devices, Bi-Level PAP devices and mechanical ventilators, the recall, and the medical warnings and advice issued by Philips, have rendered the Recalled Devices worthless to patients with sleep apnea and respiratory conditions. Individuals not using life-supporting ventilators must immediately discontinue their use of the Recalled Devices or face serious health risks as grave as organ failure or cancer. If they choose to discontinue use of the Recalled Devices, they must pay for another expensive device in order to receive effective treatment for their sleep apnea and/or respiratory conditions. Individuals using life-supporting ventilators must seek an alternative treatment before discontinuing use of the Recalled Devices.

34. Recognizing this, Philips issued the following advice to patients using any of the Recalled Devices:

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[9] *Id.*

[10] Recall Notice (Exhibit "A" hereto).

- "For patients using BiLevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."[11]

- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."[12]

35. As a result of the above, Plaintiffs and the Class and Subclass will have to undertake considerable expense to replace the Recalled Devices.

36. At no time prior to its Quarterly Report on April 26, 2021, did Philips publicly disclose that the PE-PUR Foam contained in the Recalled Devices may off-gas or degrade upon use presenting serious health risks to its users.

37. Defendants have continued to conceal when they first knew or should have known the Recalled Devices presented serious health risks to users, and that the PE-PUR Foam presented those health risks.

38. At a minimum, as a result of user reports, Defendants knew of the off-gassing and degradation of the PE-PUR Foam used in the Recalled Devices many months if not years prior to the June 14, 2021 Recall, yet continued to manufacture and sell the Recalled Devices despite knowing of the serious health risks the Recalled Devices presented to users.

39. The manuals accompanying Plaintiffs' CPAP devices did not contain any language or warnings that the devices' PE-PUR Foam could degrade or otherwise off-gas toxic substances and cause irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects. Had

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[11] Medical Device recall notification (U.S. only) / field safety notice (International Markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (Questions and answers) (emphasis in original).

[12] *Id.*

Defendants informed Plaintiffs of these risks, they would not have purchased or used the Recalled Device, which should never have been offered for sale to Plaintiffs in the first instance.

40. Without knowing the health risks associated with use of the Recalled Devices that were known or should have been known to Defendants, Plaintiffs used their Recalled Devices regularly to treat sleep apnea until learning about the Recall.

41. As a result of the health risks associated with continued use of this device and the recall, Plaintiffs' and Members of the Classes' Recalled Devices are now worthless.

TOLLING AND ESTOPPEL

42. Plaintiffs and the Classes had no way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Devices.

43. Neither Plaintiffs nor any other members of the Classes, through the exercise of reasonable care, could have discovered the conduct by Philips alleged herein. Further, Plaintiffs and members of the Classes did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

44. For these, reasons, all applicable statutes of limitation have been tolled by the discovery rule with respect to claims asserted by Plaintiffs and the Classes.

45. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Devices, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiffs and the members of the Classes.

46. Upon information and belief, Philips intended to conceal the facts and claims from Plaintiffs and members of the Classes. Plaintiffs and the members of the Classes were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have

reasonably discovered Defendants' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiffs or members of the Classes should be tolled.

CLASS ACTION ALLEGATIONS

47. Plaintiffs bring this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3). Plaintiffs seek class certification on behalf of a class defined as follows (the "Class"):

> **NATIONWIDE CLASS:** All persons in the United States who purchased or used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was recalled by Philips on June 14, 2021.

48. Plaintiffs seek certification on behalf of a subclass defined as follows (the "Subclass"):

> **PENNSYLVANIA SUBCLASS:** All persons who were or are citizens of the Commonwealth of Pennsylvania who purchased or used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was recalled by Philips on June 14, 2021.
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> **MASSACHUSETTS SUBCLASS:** All persons who were or are citizens of the Commonwealth of Massachusetts who purchased or used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was recalled by Philips on June 14, 2021.
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> **NEW JERSEY SUBCLASS**: All persons who were or are citizens of the State of New Jersey who purchased or used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was recalled by Philips on June 14, 2021

49. Plaintiffs reserve the right to modify or refine the definitions of the Classes based upon discovery of new information and in order to accommodate any of the Court's manageability concerns.

50. Excluded from the Class and Subclass are: (a) any Judge or Magistrate Judge presiding over this action and members of their staff, as well as members of their families; (b) Defendants' and Defendants' predecessors, parents, successors, heirs, assigns, subsidiaries, and any entity in which any Defendants or their parents have a controlling interest, as well as Defendants' current or former officers and directors; (c) persons who properly execute and file a

timely request for exclusion from the Class or Subclass; (d) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (e) counsel for Plaintiffs and Defendants; and (f) the legal representatives, successors, and assigns of any such excluded persons.

51. **Numerosity (Rule 23(a)(1))**. The Class and Subclasses are so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class and Subclasses, as herein identified and described, is not known, but sales figures and the Recall Notice indicate that millions of individuals have purchased the Recalled Devices.

52. **Commonality (Rule 23(a)(2))**. Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual Class and Subclass members, including the following:

- whether Defendants owed a duty of care to Plaintiffs and the Class and Subclass;
- whether the PE-PUR Foam posed health risks;
- whether Defendants knew or should have known that the PE-PUR Foam used for sound abatement posed health risks;
- whether Defendants wrongfully represented that the PE-PUR Foam used for sound abatement in the Recalled Devices was safe;
- whether the Recalled Devices retained any value post-recall;
- whether Defendants wrongfully represented that the Recalled Devices were safe to use;
- whether Defendants wrongfully failed to disclose that the PE-PUR Foam used for sound abatement in the Recalled Devices posed health risks to Recalled Device users;
- whether Defendants' representations and omissions in advertising, warranties, packaging, and/or labeling were false, deceptive, and/or misleading;
- whether those representations and omissions were likely to deceive a reasonable consumer;
- whether a reasonable consumer would consider the presence, or risk of, health risks as a material fact in purchasing one of the Recalled Devices;

- whether Defendants had knowledge that those representations and omissions were false, deceptive, and misleading;
- whether Defendants breached their express warranties;
- whether Defendants breached their implied warranties;
- whether Defendants engaged in unfair trade practices;
- whether Defendants engaged in false advertising;
- whether Defendants' conduct was negligent per se;
- whether Defendants made negligent and/or fraudulent misrepresentations and/or omissions; and
- whether Plaintiffs and the members of the Class and Subclass are entitled to actual, statutory, and punitive damages.

53. **Typicality (Rule 23(a)(3))**. Plaintiffs' claims are typical of the claims of the other members of the proposed Class and Subclasses. Plaintiffs and members of the Class and Subclasses (as applicable) suffered injuries as a result of Defendants' wrongful conduct that is uniform across the Class and Subclasses.

54. **Adequacy (Rule 23(a)(4))**. Plaintiffs' interests are aligned with the Class and Subclasses they seeks to represent. Plaintiffs have and will continue to fairly and adequately represent and protect the interests of the Class and Subclasses. Plaintiffs have retained competent counsel highly experienced in complex litigation and class actions and the types of claims at issue in this litigation, with the necessary resources committed to protecting the interests of the Class and Subclasses. Plaintiffs have no interest that is antagonistic to those of the Class and Subclasses, and Defendants have no defenses unique to Plaintiffs. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the members of the Class and Subclasses. Neither Plaintiffs nor Plaintiffs' counsel have any interest adverse to those of the other members of the Class and Subclasses.

55. **Superiority.** This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy, and joinder of all members of the Class and Subclasses is impracticable. The prosecution of separate actions by individual members of the Class and Subclasses would impose heavy burdens upon the Courts and Defendants, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class and Subclasses, and would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. Class treatment will create economies of time, effort, and expense and promote uniform decision-making.

56. **Manageability.** This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

57. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual members of the Classes, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

CLAIMS FOR RELIEF

CLAIMS ON BEHALF OF A NATIONWIDE CLASS

FIRST CLAIM FOR RELIEF

VIOLATION OF 18 U.S.C. § 1962(c) – The Philips Enterprise

58. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

59. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise, the Philips Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

60. The Philips Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including their employees, agents and external consultants. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to fraudulently market the now Recalled Devices as safe to treat sleep apnea.. The Philips Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Philips Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of these entities, including Defendants, is a "person" distinct from the Philips Enterprise.

61. Each of the Defendants, in concert with other participants in the Philips Enterprise, created and maintained systematic links for a common purpose to aid in marketing and sale of the Recalled Devices as safe to treat sleep apnea while disregarding evidence to the contrary and improperly inducing Plaintiffs and Class members to purchase the Recalled Devices based on the false representation these Recalled Devices were safe to treat sleep apnea. In doing so, the Philips Enterprise secured significant revenue over years of selling the Recalled Devices that were so inherently unsafe for their intended use that they should never have been available for sale in the first instance. All participants of the Philips Enterprise were aware of Defendants' control over its activities in falsely promoting the Recalled Devices as safe to treat sleep apnea. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

62. The Philips Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, promoted, sold, or provided the Recalled Devices to millions of individuals and entities throughout the United States.

63. The named Defendants exerted control over the Philips Enterprise and management of the affairs of the Philips Enterprise.

64. Defendants conducted and participated in the affairs of the Philips Enterprise through patterns of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

65. Defendants' fraudulent scheme consisted of their knowingly false representation that the now Recalled Devices were safe for use and inhalation as a treatment for sleep apnea.

66. Defendants' use of the mails and wires to perpetuate their fraud involved thousands of communications, including, but not limited to:

> Communications with and among the enterprise participants that misrepresented the safety and risks of Recalled Devices amongst themselves and others;
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> Communications with patients, physicians, durable medical equipment sellers, and Class Members, including Plaintiffs, inducing payments for the Recalled Devices based on the representation the Recalled Devices were safe for use and inhalation as a treatment for sleep apnea;
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> Receiving the proceeds in the course of and resulting from Defendants' improper scheme;
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> Transmittal and receipt of monies from Class Members, insurers, government programs such as Medicare and Medicaid; and
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> Transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Philips Enterprise.

67. At all times during the fraudulent scheme, Defendants had a legal and ethical obligation of candor to be honest in dealing with public and private payors, physicians and the medical community.

68. The conduct of the Philips Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decisions and activity in

connection with the Philips Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

69. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs and the Class. Each such racketeering activity was related, had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including Plaintiffs and members of the Class. Defendants' racketeering activities were part of their ongoing business and constitute a continuing threat to the property of Plaintiffs and the Class.

70. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class paid hundreds of millions of dollars for the Recalled Devices that they would not have paid had Defendants not engaged in this pattern of racketeering activity.

71. The injuries to Plaintiffs and members of the Class were directly and proximately caused by Defendants' racketeering activity.

72. Plaintiffs and the Class, directly relied on the racketeering activities of the Defendants and the Philips Enterprise. Plaintiffs and Class members, both directly and indirectly, relied on the representations and omissions as to the safety of the Recalled Devices as promoted by Defendants.

73. CPAP and BiPAP machines can only be purchased if a patient first obtains a prescription from a physician. Just as with Plaintiffs and Class Members, Defendants misrepresented the safety of the Recalled Devices failing to disclose their unsafe condition to the medical community providing prescriptions to Plaintiffs and Class Members. Accordingly, the medical community necessary to distribute the Recalled Devices to Plaintiffs and Class Members,

like Plaintiffs themselves, also directly relied on Defendants' misrepresentations and omissions regarding the safety of the Recalled Devices, and thereby proximately caused Plaintiffs' injuries.

74. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiffs and the Class for three times the damages sustained, plus the costs of this suit, including reasonable attorney's fees.

75. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs and the Class have suffered damages. The Recalled Devices were economically worthless at the point for sale by virtue of the dangerousness caused by the PE-PUR Foam degradation. Therefore, the sale of the Recalled Devices to Class Members should never had occurred, and the transaction was void ab initio.

76. Plaintiffs and the Class members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

SECOND CAUSE OF ACTION

VIOLATION OF 18 U.S.C. § 1962(d) – RICO CONSPIRACY

77. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

78. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

79. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Philips Enterprise described previously through a pattern of racketeering activity. The corporate defendants conspired to promote the Recalled Devices as a

safe treatment for sleep apnea while suppressing information about the Recalled Devices inherent health risks posed through the use of PE-PUR Foam in the Recalled Devices.

80. Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs and the Class out of money.

81. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

82. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the Class have been and are continuing to be injured in their business or property as set forth more fully above.

83. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud violations of 18 U.S.C §§ 1341 and 1346;

d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

84. Defendants' violations of the above federal laws and the effects thereof detailed above continued until the June 14, 2021 recall of the Recalled Devices. Plaintiffs and members of the Class have been injured in their property by reason of these violations in that Plaintiffs and

members of the Class have purchased the Recalled Devices for use to treat sleep apnea and been exposed to the PE-PUR Foam hazard contained therein, none of which would have occurred had Defendants not conspired to violate 18 U.S.C. § 1962(c) by claiming the Recalled Devices were safe for use as a sleep apnea treatment.

85. Injuries suffered by Plaintiffs and members of the Class were directly and proximately caused by Defendants' racketeering activity as described above.

86. Plaintiffs and the Class directly relied on the racketeering activities of the Defendants and the Philips Enterprise. Plaintiffs and the Class members, both directly and indirectly, relied on the representations that Recalled Devices were safe for use as a sleep apnea treatment.

87. As a result of the health risks associated with the use of the Recalled Devices, the Recalled Devices were economically worthless at the point for sale by virtue of the dangerousness caused by the PE-PUR Foam degradation. Therefore, the sale of the Recalled Devices to Class Members should never had occurred, and the transaction was void ab initio.

88. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant is liable to Plaintiffs and the Class for three times the damages Plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

89. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations and omissions, Plaintiffs and the Class have suffered damages. Plaintiffs and the Class members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

CLAIMS ON BEHALF OF THE STATE CLASSES

THIRD CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

90. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

91. Philips marketed and sold the Recalled Devices into the stream of commerce with the intent that the Recalled Devices would be purchased by Plaintiffs and the State Classes.

92. Philips expressly warranted, advertised, and represented to Plaintiffs and the State Classes that the Recalled Devices were safe and appropriate for human use.

93. Philips made these express warranties regarding the Recalled Devices' quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Devices' packaging and labels. These express warranties became part of the basis of the bargain that Plaintiffs and the State Classes entered into upon purchasing the Recalled Devices.

94. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Devices, were made in connection with the sale of the Recalled Devices to Plaintiffs and the State Classes. Plaintiffs and the State Classes relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Devices in deciding whether to purchase and use Philips' Recalled Devices.

95. Philips' Recalled Devices do not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

96. Philips therefore breached its express warranties by placing Recalled Devices into the stream of commerce and selling them to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and

purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, safety of the Recalled Devices, and render them worthless.

97. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled Devices, but nowhere on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiffs and members of the State Classes that they were at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the Recalled Devices.

98. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the Recalled Devices and deceptively represented that these products were safe, healthy, and appropriate for use. Philips thus utterly failed to ensure that the material representations they were making to consumers were true.

99. The adverse health effects associated with use of the Recalled Devices existed when they left Philips' possession or control and were sold to Plaintiffs and members of the State Classes. The dangers associated with use of the Recalled Devices were undiscoverable by Plaintiffs and members of the State Classes at the time of purchase of the Recalled Devices.

100. As manufacturers, marketers, advertisers, distributors and sellers of the Recalled Devices, Philips had exclusive knowledge and notice of the fact that the Recalled Devices did not conform to the affirmations of fact and promises.

101. In addition, or in the alternative, to the formation of an express contract, Philips made each of the above-described representations and omissions to induce Plaintiffs and members of the State Classes to rely on such representations and omissions.

102. Philips' affirmations of fact and promises and its omissions were material, and Plaintiffs and members of the State Classes reasonably relied upon such representations and omissions in purchasing and using the Recalled Devices.

103. All conditions precedent to Philips' liability for its breach of express warranty have been performed by Plaintiffs or members of the State Classes.

104. Affording Philips an opportunity to cure its breaches of written warranties would be unnecessary and futile here. Philips was placed on reasonable notice from user reports and its lab testing that the PE-PUR Foam in the Recalled Devices was unsafe. Philips had ample opportunity either to stop using the PE-PUR Foam or to replace the PE-PUR Foam in the Recalled Devices to make them safe and healthy for use by Plaintiffs and members of the State Classes, but failed to do so until June 14, 2021.

105. As a direct and proximate result of Philips' breaches of express warranty, Plaintiffs and members of the State Classes have been damaged because they did not receive the products as specifically warranted by Philips. The Recalled Devices were economically worthless at the point for sale by virtue of the dangerousness caused by the PE-PUR Foam degradation. Therefore, the sale of the Recalled Devices to Class Members should never had occurred, and the transaction was void ab initio.

106. Plaintiffs and members State Classes did not receive the benefit of the bargain and suffered damages at the point of sale stemming from their overpayment for the Recalled Devices.

107. Plaintiffs and the State Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their express warranties and resulting breach.

FOURTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

108. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

109. Philips are merchants engaging in the sale of goods to Plaintiffs and the State Classes.

110. There was a sale of goods from Philips to Plaintiffs and the State Classes.

111. At all times mentioned herein, Philips manufactured or supplied the Recalled Devices, and prior to the time the Recalled Devices were purchased by Plaintiffs and the State Classes, Philips impliedly warranted to them that the Recalled Devices were of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and omissions made on the Recalled Devices' labels and packaging, including that the Recalled Devices were safe and appropriate for human use. Plaintiffs and the State Classes relied on Philips' promises and affirmations of fact and omissions when they purchased and used the Recalled Devices.

112. Contrary to these representations and warranties, the Recalled Devices were not fit for their ordinary use and did not conform to Philips' affirmations of fact and promises and omissions because use of the Recalled Devices is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

113. Philips breached its implied warranties by selling Recalled Devices that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled Devices was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

114. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled Devices through, at a minimum, user reports submitted to Philips and through lab testing.

115. Privity exists because Philips impliedly warranted to Plaintiffs and the Class through the warranting, packaging, advertising, marketing, and labeling that the Recalled Devices were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled Devices.

116. As a direct and proximate result of Philips' conduct, Plaintiffs and the Class and Subclass have suffered actual damages in that the Recalled Devices were economically worthless at the point for sale by virtue of the dangerousness caused by the PE-PUR Foam degradation. Therefore, the sale of the Recalled Devices to Class Members should never had occurred, and the transaction was void ab initio.

117. Each Recalled Device purchased is now worthless, and none would not have purchased at all had the known attendant health risks associated with the use of each Recalled Device been known to Plaintiffs and the State Classes.

118. Plaintiffs and the State Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their implied warranties and resulting breach.

FIFTH CLAIM FOR RELIEF

VIOLATION OF MAGNUSON-MOSS WARRANTY ACT,

15 U.S.C. §2301, *et seq*. ("MMWA")

(on behalf of the State Classes)

119. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

120. The MMWA provides a private right of action by purchasers of consumer products against retailers who, inter alia, fail to comply with the terms of an implied or written warranty. 15 U.S. C. § 2310(d)(1). As alleged herein, Defendants failed to honor their express and implied warranties with regard to the Recalled Devices.

121. The Recalled Devices are consumer products, as that term is defined in 15 U.S.C. § 2301(1).

122. Plaintiffs and members of the State Classes are consumers, as that term is defined in 15 U.S.C. § 2301(3).

123. Philips is a supplier and warrantor, as those terms are defined in 15 U.S.C. § 2301(4)-(5).

124. The MMWA provides a cause of action for breach of warranty or other violations of the MMWA. Philips breached its express and/or implied warranty of merchantability for the Recalled Devices, as alleged here, which cannot be disclaimed under the MMWA, 15 U.S.C. § 2308(a)(1), and by selling the Recalled Devices as safe for use to treat sleep apnea when they patently were not. Plaintiffs and the State Class Members suffered damages in paying for the Recalled Devices, which were economically worthless at the time of sale due to their now admitted health risks. 15 U.S.C. § 2310(d)(1)-(2).

125. Philips was provided notice of the claims raised by Plaintiffs and was afforded a reasonable opportunity to cure. Philips failed to cure harm caused by their breaches of warranty. Until Plaintiffs' representative capacity is determined, notice an opportunity to cure through Plaintiffs, and on behalf of any State Class, can be provided under 15 U.S.C. § 2310(e).

126. Philips acts and omissions in violation of the MMWA are "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts of practices in or affecting commerce," and they are harmful. 15 U.S.C. § 2310(b); 15 U.S.C. § 45(a).

127. Plaintiffs and the State Classes have suffered, and are entitled to recover, damages as a result of Philips' breach of express and/or implied warranties and violations of the MMWA.

128. Plaintiffs also seek an award of costs and expenses, including attorneys' fees, under the MMWA to prevailing consumers in connection with the commencement and prosecution of this action. 15 U.S.C. § 2310(d)(2). Plaintiffs and the prospective State Class Members intend to seek such an award, including expert witness costs and other recoverable costs, as prevailing consumers at the conclusion of this lawsuit.

SIXTH CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION

129. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

130. Philips had a duty to Plaintiffs and the State Classes to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices.

131. Philips breached its duty to Plaintiffs and the State Classes by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiffs and the State Classes that did not have the qualities, characteristics, and suitability for use as advertised by Philips and by failing to promptly remove the Recalled Devices from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled Devices.

132. Philips knew or should have known that the qualities and characteristics of the Recalled Devices were not as advertised or suitable for their intended use and were otherwise not

as warranted and represented by Philips. Specifically, Philips knew or should have known that: (a) the use of the Recalled Devices was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) the Recalled Devices were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and (c) the Recalled Devices were otherwise not as warranted and represented by Philips.

133. As a direct and proximate result of Philips' conduct, Plaintiffs and the Class and Subclass have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known they contained PE-PUR Foam that could cause users of the Recalled Devices to suffer adverse health effects, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

134. Plaintiffs and the Class and Subclass seek actual damages, attorneys' fees, costs, and any other just and proper relief available.

SEVENTH CLAIM FOR RELIEF

PENNSYLVANIA UNFAIR TRADE PRACTICES AND

CONSUMER PROTECTION LAW, 73 Pa. Cons. Stat. Ann. §§ 201-1, et seq.

(on behalf of the Pennsylvania Class)

135. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

136. At all times mentioned herein, Philips engaged in "trade" or "commerce" in Pennsylvania, as defined by 73 Pa. Cons. Stat. Ann. § 201-2(3), in that they advertised, offered for sale, and sold goods, property, or services primarily for personal, family, or household purposes, and advertised, solicited, offered for sale, and sold "services," "property," "article[s]," "commodity[ies]," or "thing[s] of value" in Pennsylvania.

137. Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTCPL"), 73 Pa. Cons. Stat. Ann. § 201-3 provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce...are hereby declared unlawful."

138. For the reasons discussed herein, Philips violated and continues to violate the UTCPL by engaging in the herein described unconscionable, deceptive, unfair acts or practices proscribed by UTCPL §§ 201-1, et seq. Philips' acts and practices, including its material omissions, described herein, were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

139. Philips repeatedly advertised on the labels and packing for the Recalled Devices, on Philips' websites, and through national advertising campaigns, among other items, that the Recalled Devices were safe and fit for human use. Philips failed to disclose the material information that the PE-PUR Foam used in the Recalled Devices, and therefore the Recalled Devices themselves, were unsafe and unfit for human use.

140. Philips' representations and omissions were material because they were likely to deceive reasonable consumers to induce them to purchase and use the Recalled Devices without being aware that the PE-PUR Foam used in the Recalled Devices, and therefore the Recalled Devices themselves, were unsafe and unfit for human use. As a direct and proximate result of Philips' unfair and deceptive acts or practices, Plaintiffs and the Pennsylvania Class Members suffered damages by purchasing the Recalled Devices because they would not have purchased the Recalled Devices had they known the truth, and they received a product that was worthless because it contains unsafe PE-PUR Foam which can cause a number of adverse health effects, including organ failure and cancer.

141. Philips' deceptive trade practices caused injury in fact and actual damages to Plaintiffs and members of the Pennsylvania Class in the form of the loss or diminishment of value of the Recalled Devices that Plaintiffs, Class Members, and Subclass Members purchased, which allowed Defendants to profit at the expense of Plaintiffs, Class Members, and Subclass Members. The injuries Plaintiffs and Subclass Members sustained were to legally protected interests. The gravity of the harm of Philips' actions is significant and there is no corresponding benefit to consumers of such conduct.

142. As a result of the health risks associated with the use of the Recalled Devices, the Recalled Devices were economically worthless at the point for sale by virtue of the dangerousness caused by the PE-PUR Foam degradation. Therefore, the sale of the Recalled Devices to Class Members should never had occurred, and the transaction was void ab initio.

143. Plaintiffs, Class Members, and Subclass Members seek relief for the injuries they have suffered as a result of Defendants' unfair and deceptive acts and practices, as provided by 73 Pa. Cons. Stat. Ann. § 201-9.2 and applicable law.

EIGHTH CLAIM FOR RELIEF

UNFAIR AND DECEPTIVE PRACTICES VIOLATION

OF MASS. GEN. LAWS CH. 93A

(on behalf of the Massachusetts Class only)

144. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

145. At all material times, Plaintiffs and Defendants were engaged in "trade or commerce" as those terms are defined by Massachusetts General Laws, Ch. 93A, §§ 2 and 9.

146. Defendants engaged in unfair acts and deceptive business practices, including but not limited to the following: (a) representing the Recalled Devices as safe to treat sleep apnea; (b)

omitting any disclosure of the use of PE-PUR Foam and its serious health risks presented by its use in the Recalled Devices; (c) failing to honor the warranties applicable to the Recalled Devices; and (d) claiming the Recalled Devices are fit for human use when they are not.

147. The acts and practices of Defendants described herein constitute unfair and deceptive acts and practices as prohibited by Mass. Gen. Laws, Ch. 93A.

148. The use of these unfair and deceptive acts and practices by Defendants were willing, knowing and intentional.

149. All Defendants were served with a demand letter pursuant to the requirements of Mass. Gen. Laws, Ch. 93A, § 9. See Exhibit B.

150. Defendants have failed to tender the relief requested or any other form of relief to remediate the issues raised in this action.

151. As a result of the health risks associated with the use of the Recalled Devices, the Recalled Devices were economically worthless at the point for sale by virtue of the dangerousness caused by the PE-PUR Foam degradation. Therefore, the sale of the Recalled Devices to Class Members should never had occurred, and the transaction was void ab initio.

152. Plaintiffs, Class Members, and Subclass Members seek relief for the injuries they have suffered as a result of Defendants' unfair and deceptive acts and practices, as provided by Mass. Gen. Laws, Ch. 93A, including treble damages, attorneys' fees and costs.

NINETH CLAIM FOR RELIEF

VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT,

N.J.S.A. § 56:8-2, et seq. ("CFA")

On Behalf of the New Jersey Sub-Class

153. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

154. Plaintiffs and other members of the New Jersey Sub-Class are "consumers" within the meaning of the New Jersey Consumer Fraud Act.

155. The Recalled Devices are "merchandise" within the meaning of the CFA, as they are goods that are offered directly or indirectly to the public for sale.

156. At all relevant times, Defendants conducted trade and commerce in New Jersey and elsewhere within the meaning of the CFA.

157. The CFA is, by its terms, a cumulative remedy, such that remedies under its provisions can be awarded in addition to those provided under other remedies.

158. Defendants have engaged in deceptive, unconscionable, unlawful, unfair, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion, and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR Foam degradation.

159. Defendants knew the dangerousness caused by the PE-PUR Foam degradation in the Recalled Devices, and did not disclose it while misrepresenting the Recalled Devices as safe.

160. Defendants intended that consumers like Plaintiffs and members of the New Jersey Sub-Class rely on its deceptive, false and misleading misrepresentations or omissions of material fact in order to sell the Recalled Devices.

161. Defendants intended that Plaintiffs and the other members of the New Jersey Sub-Class to rely on its acts of concealment and omissions by purchasing the Recalled Devices at full price rather than paying less or purchasing a competitors' PAP Device.

162. Had Defendants disclosed all material information regarding the Recalled Devices to Plaintiffs and other members of the New Jersey Sub-Class, they would not have purchased the Recalled Devices, or they would have paid less for them.

163. Defendants' conduct had an impact on the public interest because the acts were part of a generalized course of conduct affecting numerous consumers.

164. As a result of the foregoing acts, omissions, and practices, Plaintiffs and other members of the New Jersey Sub-Class have suffered an ascertainable loss by purchasing and/or using the Recalled Devices they would not have otherwise purchased or paid less for, which are unable to perform their essential function for their expected useful life, have lost value as a result of the Recall, and present a risk of safety to Plaintiffs and members of the New Jersey Sub-Class. Plaintiffs are entitled to recover such damages, together with appropriate penalties, including treble damages, attorneys' fees, and costs of suit.

TENTH CLAIM FOR RELIEF

MEDICAL MONITORING

(on behalf of the State Classes)

165. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

166. At all relevant times, the Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and

therefore owed a duty of reasonable care to avoid causing harm to those that used them, such as Plaintiffs.

167. Defendants have reported that users of the Recalled Devices face risks of serious injury from the degradation of PE-PUR Foam contained in the Recalled Devices. Degradation of PE-PUR Foam may be caused by exposure to chemical emissions from the foam material, high heat and high humidity environments in certain regions, and cleaning methods such as ozone may accelerate potential degradation.

168. When PE-PUR Foam degrades into particles that may enter the device's pathway and be ingested or inhaled by users of the devices, users face significantly increased risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of degraded foam exposure include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects.

169. The off-gassing of chemicals from the PE-PUR Foam contained in the Recalled Devices poses risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of exposure to off-gassing from PE-PUR Foam include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

170. The absence of visible particles does not mean that PE-PUR Foam breakdown has not already begun. Philips has reported that lab analysis of the degraded foam reveals the presence of harmful chemicals including: TDA, TDI, and DEG.[13] TDI is a powerful irritant to the mucous

[13] Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed June 27, 2021).

membranes of the eyes and gastrointestinal and respiratory tracts,[14] and has been reported to cause Occupational Asthma.[15] Exposure to TDA may result in ataxia, tachycardia, nausea, vomiting, convulsions, and respiratory depression.[16] TDA can cause chemical cyanosis (i.e., bluish discoloration of the skin) by converting hemoglobin to methemoglobin. This compound can also cause fatty degeneration of the liver.[17] TDA and TDI are potential carcinogens.[18] Repeated exposure to DEG has been associated with damage to the kidneys and renal failure.[19]

171. The FDA has designated the Phillips' Recall under its most serious classification, which means there is a reasonable probability that past or continued use of the device could lead to serious health issues.

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[14] The National Institute for Occupational Safety and Health (NIOSH) Current Intelligence Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity, DHHS (NIOSH) Publication Number 90-101 (Dec. 1989); see also Gunnar Skarping, et al., Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluene diisocyanate, Dep't of Occupational and Environmental Medicine, University Hospital, S-221 85 Lund, Sweden (1990); https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/.

[15] Bernstein, David I, Occupational asthma: Definitions, epidemiology, causes, and risk factors, Wolters Kluwer, UpToDate.com.

[16] NIOSH, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity; see also Skarping, Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluene diisocyanate; https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/.

[17] NIOSH, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity.

[18] *Id.* ("The excess cancer risk for workers exposed to TDI and TDA has not yet been quantified, but the probability of developing cancer should be decreased by minimizing exposure.").

[19] Greg M. Landry, Diethylene glycol-induced toxicities show marked threshold dose response in rats, Toxicology and Applied Pharmacology 282 (2015) 244-251 ("DEG has recently been involved in several mass epidemics of renal failure and death world-wide (O'Brien et al., 1998; Schier et al., 2013). DEG poisoning clinically manifests in metabolic acidosis, hepatotoxicity, renal failure, and peripheral neuropathy, with the hallmark being acute renal failure involving proximal tubule cell necrosis and cortical degeneration (Schep et al., 2009)"); Cohen, Jeffrey A., Demyelinating Diseases of the Peripheral Nerves, Nerves and Nerve Injuries (2015) ("When consumed, DEG causes severe systemic and neurologic complications, including coma, seizures, peripheral neuropathy, and hepatorenal failure.").

172. Because of the serious health risks known to be associated with the use of the Recalled Devices, doctors have been inundated with calls from worried patients. Replacements for the Recalled Devices are not readily available as prices for machines made by Philips' main competitor, ResMed Inc., have shot up and the devices are becoming more difficult to get. Class Members are therefore left with a series of unacceptable choices feeling ping-ponged between Philips and other medical-device suppliers who cannot supply a replacement, doctors and insurers who are addressing millions of the identical concerns about the Recalled Devices, and are now taking matters into their own hands, either by continued necessary use of the Recalled Devices, or by removing the foam themselves to use the Recalled Devices.

173. As a direct and proximate result of Defendants' conduct, Plaintiffs have been exposed to substantially increased risks of serious injury from off-gassing and/or degradation of PE-PUR Foam in the Recalled Devices, which is beyond normal background levels of risk.

174. As a direct and proximate result of Defendants' conduct, Plaintiffs have a significantly increased risk of suffering serious injury or contracting a serious latent disease, and suffering further injury at an unknown date in the future. Such injuries include cancer and organ failure, among others currently unknown or just being discovered.

175. Monitoring procedures exist that makes the early detection of damage from degraded and/or off-gassed PE-PUR Foam possible. These procedures are different from that normally recommended in the absence of the exposure. These monitoring procedures include non-routine surveillance studies, laboratory testing, and physical examinations, and would be reasonably necessary according to contemporary scientific principles.

176. Existing medical research indicates that exposure to TDI, TDA, and DEG, which Philips has found to exist in off-gassed or degraded PE-PUR Foam, can cause serious, life-

threatening and permanent injuries. Philips has received reports from users of the Recalled Devices of headache, upper airway irritation, cough, chest pressure and sinus infection. The exposure to the defects inherent in the Recalled Devices has occurred for users, such as Plaintiffs, but the full extent of the injuries will not manifest until later in the Plaintiffs' life. Thus, because of Defendants' conduct, it is reasonably necessary that Plaintiffs be placed under period diagnostic testing beyond that normally recommended in the absence of use of the Recalled Devices.

177. Plaintiffs demand judgment against Defendants for medical monitoring damages to diagnose injuries caused by the Recalled Devices at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

ELEVENTH CLAIM FOR RELIEF

UNJUST ENRICHMENT

(on behalf of the State Classes)

178. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

179. Plaintiffs and the State Classes conferred substantial benefits on Philips through their purchase of the Recalled Devices.

180. Philips knowingly and willingly accepted and enjoyed these benefits.

181. Philips either knew or should have known that the payments rendered by Plaintiffs and the State Classes were given with the expectation that the Recalled Devices would have the qualities, characteristics, and suitability for use represented and warranted by Philips. As such, it would be inequitable for Philips to retain the benefit of the payments under these circumstances.

182. Philips' acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Philips to retain the benefits without payment of the value to Plaintiffs and the State Classes.

183. Plaintiffs and the State Classes are entitled to recover from Philips all amounts wrongfully collected and improperly retained by Defendants, plus interest thereon.

184. Plaintiffs and the State Classes seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, pray for judgment against Philips as to each and every count, including:

A. An order certifying this action and the National Class and State Classes requested herein as a class action, designating Plaintiffs as representatives of the Classes, as applicable, and appointing Plaintiffs' counsel as counsel to the Classes;

B. An order declaring that Philips' actions constitute violations of the claims for relief asserted herein, and that Philips is liable to Plaintiffs and the Classes, as described herein, for damages arising therefrom;

C. A judgment awarding Plaintiffs and members of the Classes all appropriate damages in an amount to be determined at trial;

D. A judgment awarding Plaintiffs and the State Classes medical monitoring damages;

E. A judgment awarding Plaintiffs and the Classes prejudgment and post-judgment interest, as permitted by law;

F. A judgment awarding Plaintiffs and the Classes costs and fees, including attorneys' fees, as permitted by law; and

G. Grant such other legal, equitable or further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury for all issues so triable.

DATED: September 23, 2021

Respectfully submitted,

/s/ Simon B. Paris

Simon B. Paris, Esq. (Atty. ID# 04982-1996)
Patrick Howard, Esq. (Atty. ID# 02280-2001)
SALTZ MONGELUZZI & BENDESKY, PC
1650 Market Street, 52nd Floor
One Liberty Place
Philadelphia, PA 19103
Telephone: 215-496-8282
Facsimile: 215-754-4443
Email: sparis@smbb.com
Email: phoward@smbb.com

Francesco P. Trapani, Esquire
KREHER & TRAPANI LLP
Two Penn Center Plaza, Suite 900
1500 JFK Boulevard
Philadelphia, PA 19102
Telephone: (215) 907-7289
Facsimile: (215) 907-7287
Email: frank@krehertrapani.com

Attorneys for Plaintiffs